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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of	:	**Confirmation No. 2333**
Toshimitsu ISHIKAWA et al.	:	Attorney Docket No. 99_1012A
Serial No. 09/393,168	:	Group Art Unit 1616
Filed September 10, 1999	:	Examiner Edward J. Webman
SOFT CAPSULE	:	**Mail Stop Appeal Brief - Patents**

SUBMISSION OF AMENDED APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEE FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975.

Sir:

In response to the PTO paper mailed October 25, 2006, attached hereto is an Amended Appeal Brief, consisting of 12 pages including the Claims Appendix, Evidence Appendix and Related Proceedings Appendix. Each of the Evidence Appendix and Related Proceedings Appendix state "None." as required.

Respectfully submitted,

Toshimitsu ISHIKAWA et al.

By: _____
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November 3, 2006

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Sir:

This is an appeal from the final rejection of claims 1-22.

Real Party in Interest

The real party in interest is SANKYO CO., LTD., the Assignee of the above-identified application.

Related Appeals and Interferences

There are no related appeals or interferences.

Status of Claims

The only claims pending in the application are claims 1-22, which are the appealed claims, as set forth in the Claims Appendix attached hereto. Claims 1-22 are rejected.

Status of Amendments

No amendments to the claims were made subsequent to final rejection.

Summary of Claimed Subject Matter

The only independent claims on appeal are claims 1, 19 and 20.

Claim 1 is directed to a soft capsule encapsulating a medicinal liquid (page 2, line 10) comprising a dietary fiber in an amount of 5 to 90% by weight based on a whole composition of the medicinal liquid (page 2, lines 25-27), wherein the medicinal liquid is in the form of a suspension (page 8, line 16; page 10, line 34; and page 11, line 8) which is homogenized (page 6, line 26) and the dietary fiber facilitates suspension of components of the medicinal liquid and stabilizes the suspension (page 4, lines 1-7).

Claim 19 is the same as claim 1 except that it uses "consisting essentially of" language instead of the term "comprising" in claim 1; and claim 19 also requires a material of limited oil-solubility other than the dietary fiber in an amount of 1 to 80% by weight based on the whole composition of the medicinal liquid (page 3, lines 11-14).

Claim 20 is the same as claim 19, except that the amount of dietary fiber is 5 to 60% by weight (page 2, line 29); the amount of material of limited oil-solubility is 1 to 70% by weight (page 3, line 17); and claim 20 further requires either a fat and oil material or an oil-soluble material in an amount of 1 to 50% by weight based on the whole composition of the medicinal liquid (page 3, lines 18-21).

Grounds of Rejection to be Reviewed on Appeal

Claims 1-22 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Miskel et al. (USP 3,851,051) in view of Tanner et al. (USP 5,569,466).

The Examiner takes the position that Miskel et al. teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility, without any dispersion stabilizer or oil material or oil soluble material; and further discloses that the soft capsule contains a fat and oil material or oil-soluble material. The Examiner recognizes that Miskel et al. do not

teach a homogenous mixture of the medicinal liquid in the soft capsule, but takes the position that Tanner et al. teach homogenization of actives and solubilizing agents, and also disclose water. Accordingly, the Examiner takes the position that it would have been obvious to make a soft gel capsule comprising citrus pectin to achieve high stability in view of Miskel et al., and that Tanner et al. teach that homogenization is well known in the art of making a soft gel capsule, which would provide a stable mixture.

Argument

According to Miskel et al., aqueous solutions or suspensions of active ingredients are prepared by using water as a solvent. In the soft capsule of Miskel et al., the macromolecular gel-lattice matrix is a rigid gel system which sets upon cooling and/or drying so as to reach a stable equilibrium with respect to the shell moisture content. According to the present invention, such a drying operation is not required and water is not necessarily required. In addition, Miskel et al. does not mention that addition of the pectin increases the amount of the active ingredients contained in the aqueous solution or suspension.

In the soft elastic gel capsule of Tanner et al., maltitol syrup is used as a carrier medium for active ingredients added thereto to form a homogenized mixture in a solution or suspension form. When the maltitol syrup of Tanner et al. is applied to the gel-lattice vehicle of Miskel et al., they are incompatible with each other in terms of their functions. Therefore, it is unreasonable to combine the teachings of Miskel et al. and Tanner et al. Ex parte Hartman, 186 USPQ 366.

The Examiner takes the position that Miskel et al. teach a soft capsule comprising a water-soluble dietary fiber (citrus pectin) and a material of limited-oil solubility, without the presence of an dispersion stabilizer and fat and oil material or oil-soluble material.

However, the citrus pectin, which the Examiner says is a dietary fiber, is used as a part of the material for the macromolecular gel-lattice matrix to gelate an aqueous solution or suspension contained within the matrix. In the final form of the soft capsule of Miskel et al., the macromolecular gel-lattice matrix has become a rigid gel system.

On the other hand, in the presently claimed invention, the dietary fiber facilitates suspension of the components of the medicinal liquid and stabilizes the suspension, thus being different from the citrus pectin (dietary fiber) of Miskel et al.

Although the disclosure at column 3, lines 40-44 of Miskel et al. teaches a stable soft gelatin capsule having a water-containing solution or suspension of an active ingredient in the fill, the more detailed disclosure at column 3, lines 48-52 states that the capsule contains a fluid or semi-fluid fill composed of a macro-molecular gel-lattice matrix as a carrier for the aqueous solution or suspension of a chemical compound or medicament. A similar disclosure in set forth at the bottom of column 3, indicating that the gel-lattice matrix contains the aqueous solution or suspension.

Thus, in accordance with Miskel et al., the dietary fiber is not part of the aqueous solution or suspension, but rather, is part of the rigid gel system formed when the gel-lattice matrix is cooled (column 4, lines 1-6).

On the other hand, in accordance with the present invention, the medicinal liquid is a homogenized suspension containing both the dietary fiber and the material of limited oil-solubility (e.g. medicament). This is in contrast to Miskel et al. in which the dietary fiber is not in a homogenized suspension with the aqueous solution or suspension of the medicament, but rather, the dietary fiber is part of a rigid gel system which forms a matrix for the aqueous solution or suspension of the medicament.

One of the advantages of the present invention is that it permits the capsule to have a higher content of the material of limited oil-solubility (e.g. medicament), as noted in the first full paragraph on page 7 of the specification. There is absolutely no suggestion in Miskel et al. that this advantage could be achieved by incorporating the dietary fiber in the suspension of the material of limited oil-solubility.

The Examiner recognizes that Miskel et al. do not teach a homogeneous mixture of the medicinal liquid in the soft capsule. The Examiner then applies the Tanner et al. reference for a teaching of homogenization of actives and solubilizing agents, and the Examiner takes the position that it would have been obvious to make a soft gel capsule comprising citrus pectin to achieve

high stability in view of Miskel. As to the claimed homogenization, the Examiner argues that Tanner et al. teach that homogenization is well known in the art of making a soft gel capsule, and that one of ordinary skill in the art would recognize that homogenization provides a stable mixture.

However, in the present invention, the homogenized suspension contains the dietary fiber, whereas in Miskel et al. the rigid gel system contains the dietary fiber. It is this rigid gel system that forms a matrix for the medicament. If the contents of the soft gel capsule of Miskel et al. were homogenized as suggested by the Examiner, the result would be to destroy the rigid gel system, i.e. matrix, which represents the inventive concept of Miskel et al. References cannot properly be combined if the effect of such combination would destroy the invention on which one of the references is based. Ex parte Hartmann, *supra*. The only way to achieve a homogenized suspension of the contents of the soft capsule of Miskel et al. would be to destroy the matrix, i.e. rigid gel system. Accordingly, one of ordinary skill in the art would not combine the references in the manner suggested by the Examiner.

More particularly, in the soft capsules of Miskel et al., the macromolecular compounds are not in the form of a liquid type suspension as required in the soft capsule of the present invention, but instead in the form of a rigid gel system. The rigid gel system of Miskel et al. is formed by preparing a macromolecular gel-lattice matrix comprised of 30-50% water which contains active chemical compounds, and then cooling and drying the matrix to set to the rigid system. That is, in order to formulate the macromolecular gel lattice matrix, a considerable amount of water is always necessary.

The soft elastic gelatin capsules of Tanner et al. employ a maltitol syrup carrier system in which an active agent is dissolved or suspended in the form of a homogenized mixture.

In Miskel et al. and Tanner et al., the important function of each of the carrier systems performed in encapsulating the active agent(s) in a soft gelatin shell is based on the respective constructions thereof which are different from each other. It is clear that the suspension in the form of a homogenized mixture of Tanner et al. cannot be applied to the rigid gel system of

Miskel et al. Accordingly, the combination of the teachings of Miskel et al. and Tanner et al. as indicated by the Examiner is unreasonable.

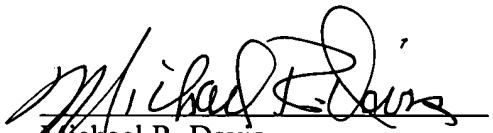
Regarding Example 50 of Miskel et al., specifically mentioned by the Examiner, although the Examiner considers the disclosed vitamin E to be an oil-soluble material, Appellants note that Example 50 discloses d-alpha tocopheryl polyethylene glycol succinate, which is a salt that is soluble in water rather than in oil.

For these reasons, Appellants take the position that the presently claimed invention is clearly patentable over the applied references, and therefore, the rejection set forth by the Examiner should be reversed.

The requisite fee of $250.00 was submitted June 28, 2006.

Respectfully submitted,

Toshimitsu ISHIKAWA et al.

By: 

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Claims Appendix

1. A soft capsule encapsulating a medicinal liquid comprising a dietary fiber in an amount of 5 to 90% by weight based on a whole composition of the medicinal liquid;

wherein said medicinal liquid is in the form of a suspension which is homogenized and the dietary fiber facilitates suspension of components of the medicinal liquid and stabilizes the suspension.

2. A soft capsule as defined in claim 1, wherein said dietary fiber is contained in an amount of 5 to 60% by weight based on the whole composition of said medicinal liquid.

3. A soft capsule as defined in claim 1, wherein said dietary fiber is either a micronized vegetable fiber or a water-soluble dietary fiber.

4. A soft capsule as defined in claim 2, wherein said dietary fiber is either a micronized vegetable fiber or a water-soluble dietary fiber.

5. A soft capsule as defined in claim 1, wherein said soft capsule is substantially free of any dispersion stabilizer.

6. A soft capsule as defined in claim 2, wherein said soft capsule is substantially free of any dispersion stabilizer.

7. A soft capsule as defined in claim 3, wherein said soft capsule is substantially free of any dispersion stabilizer.

8. A soft capsule as defined in claim 4, wherein said soft capsule is substantially free of any dispersion stabilizer.

9. A soft capsule as defined in claim 1, wherein said soft capsule is substantially free of any fat and oil material or oil-soluble material.

10. A soft capsule as defined in claim 2, wherein said soft capsule is substantially free of any fat and oil material or oil-soluble material.

11. A soft capsule as defined in claim 3, wherein said soft capsule is substantially free of any fat and oil material or oil-soluble material.

12. A soft capsule as defined in claim 5, wherein said soft capsule is substantially free of any fat and oil material or oil-soluble material.

13. A soft capsule as defined in claim 1, further comprising either a fat and oil material or an oil-soluble material in an amount of 50% or less by weight based on the whole composition of said medicinal liquid.

14. A soft capsule as defined in claim 2, further comprising either a fat and oil material or an oil-soluble material in an amount of 50% or less by weight based on the whole composition of said medicinal liquid.

15. A soft capsule as defined in claim 3, further comprising either a fat and oil material or an oil-soluble material in an amount of 50% or less by weight based on the whole composition of said medicinal liquid.

16. A soft capsule as defined in claim 5, further comprising either a fat and oil material or an oil-soluble material in an amount of 50% or less by weight based on the whole composition of said medicinal liquid.

17. A soft capsule as defined in claim 9, further comprising a material of limited oil-solubility other than the dietary fiber in an amount of 1 to 80% by weight based on the whole composition of said medicinal liquid.

18. A soft capsule as defined in claim 14, further comprising a material of limited oil-solubility other than the dietary fiber in an amount of 1 to 70% by weight based on the whole composition of said medicinal liquid;

said fat and oil material or oil-soluble material being contained in an amount of 1 to 50% by weight based on the whole composition of said medicinal liquid.

19. A soft capsule encapsulating a medicinal liquid consisting essentially of:

a dietary fiber in an amount of 5 to 90% by weight based on a whole composition of the medicinal liquid; and

a material of limited oil-solubility other than the dietary fiber in an amount of 1 to 80% by weight based on the whole composition of said medicinal liquid;

wherein said medicinal liquid is in the form of a suspension which is homogenized and the dietary fiber facilitates suspension of components of the medicinal liquid and stabilizes the suspension.

20. A soft capsule encapsulating a medicinal liquid consisting essentially of:

a dietary fiber in an amount of 5 to 60% by weight based on a whole composition of the medicinal liquid;

a material of limited oil-solubility other than the dietary fiber in an amount of 1 to 70% by weight based on the whole composition of said medicinal liquid; and

either a fat and oil material or an oil-soluble material in an amount of 1 to 50% by weight based on the whole composition of said medicinal liquid;

wherein said medicinal liquid is in the form of a suspension which is homogenized and the dietary fiber facilitates suspension of components of the medicinal liquid and stabilizes the suspension.

21. A soft capsule as defined in claim 17, wherein said material of limited oil-solubility comprises a powder material or a soft extract material.

22. A soft capsule as defined in claim 18, wherein said material of limited oil-solubility comprises a powder material or a soft extract material.

Evidence Appendix

None.

Related Proceedings Appendix

None.